

SERIAL NO. 10/643,006

PATENT APPLICATION

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	LOVETT et al.	Examiner:	Nguyen, H.
Serial No.:	10/643,006	Group Art Unit:	3736
Filed:	August 18, 2003	Docket No.:	GUID.060PA
Confirmation No.:	2975	Customer No.:	51294
Title:	SLEEP STATE CLASSIFICATION		

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**APPELLANT'S STATEMENT IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented by Appellant in compliance with the USPTO *Official Gazette* Notice of July 12, 2005 entitled "New Pre-Appeal Brief Conference Pilot Program". Appellant is requesting a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and are without merit. Appellant's request is based upon a clear legal or factual deficiency in the rejections. As such, Appellant believes this request for pre-appeal review is appropriate.

In the Final Office Action of June 8, 2010, claims **86, 88, 89, 91-93, 95-99, 101, 104, 106, 107, 109, 112-117, and 121** were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,902,250 (Verrier et al.), hereinafter "Verrier", in view of U.S. Patent Application Publication US 2005/0119711 (Cho et al.), hereinafter "Cho", and further in view of U.S. Patent Application Publication US 2003/0083241 (Young). Other dependent claims were rejected under 35 U.S.C. §103(a) as being unpatentable over Verrier in view of Cho and Young, and further in view of other secondary references.

Independent method claim **86** recites *inter alia* “sensing pectoral muscle tone using a sensor disposed on a cardiac rhythm management device implanted in a pectoral region” and “detecting REM sleep status based on the pectoral muscle tone”. Independent device claim **104** similarly recites a “first sensor disposed on the implantable cardiac rhythm management device, the first sensor configured to sense muscle tone in a pectoral region of the patient and to detect REM sleep status based on the pectoral muscle tone”.

On page 4 of the Final Office Action, the Examiner appears to acknowledge that neither Verrier nor Cho discloses sensing pectoral muscle tone, or detecting REM sleep status based on the pectoral muscle tone. The Examiner however then characterizes Young as follows:

“Young teaches that sensing a muscle tone in a pectoral region is a positive sign of REM-sleep which is typically accompanied by muscle atonia in that region (¶0047).” (p. 4 of the Office Action)

and

“... Young teaches sensing muscle tone or lack thereof – atonia – in a pectoral region of a patient to determine REM sleep status.” (p. 8 of the Office Action)

Applicants strongly but respectfully disagree with these characterizations of Young. The cited paragraph 0047 of Young contains the following muscle-related discussion:

“... Also in the course of normal REM-sleep, and to lesser degree in deep NREM-sleep, atonia of the postural muscles develops and extends to the muscles of the upper airway leading to a collapse of the soft tissues, resulting in upper airway obstruction of varying degree. The teaching of Werth et al., indicates that muscle atonia in non-REM sleep can be readily produced in normal individuals by selective REM sleep deprivation (Werth, et al., 2002).”

As explained more fully in Appellant’s Response dated August 9, 2010, nowhere in the cited paragraph does Young mention actually sensing muscle tone. Further, nowhere in the cited paragraph does Young teach or even hint at using a sensed muscle tone so as to detect REM sleep status. Despite Young’s discussion of a relationship between REM sleep and muscle atonia, Young does *not* recognize the utility of sensing the muscle tone and then using the sensed muscle tone to detect REM sleep. The Final Office Action is incorrect when it says that “Young teaches sensing muscle tone ... in a pectoral region of a patient to determine REM sleep status.”

Since the rejection of independent claims 86 and 104 is based on this misinterpretation of Young, and since neither Young nor the other asserted references Verrier or Cho teach the above-quoted features of claims 86 and 104, the combination of Verrier, Cho, and Young cannot logically teach those features either, and the rejection cannot be sustained.

In the Advisory Action dated August 24, 2010, the Examiner provides further rationale for the rejection by reasoning that:

“... the teachings of Young are not considered just by what is explicitly disclosed but also by what the teachings suggest to one of ordinary skill in the art. It is clear that Young discloses that REM sleep is characterized by a lack in muscle tone – muscle atonia – in the pectoral region. Since Verrier et al teach detecting conditions representative of and thus detecting REM sleep to determine sleep classification, and Cho et al teach an analogous device which is a cardiac rhythm management device implanted within the pectoral region of a patient with a sensor disposed thereon, those teachings in addition with those taught by Young et al would strongly suggest to one of ordinary skill in the art that by modifying all three references such that a sensed muscle tone is detected, the lack thereof would constitute an equally effective mechanism to signify the presence of REM and thus enable sleep classification as set forth by Verrier et al.”

The further rationale in the Advisory Action also appeals to various principles relating to obviousness, such as:

- “There is no requirement that an express, written motivation to combine must appear in prior art references before a finding of obviousness.”
- “... motivation to combine prior art references may exist in the nature of the problem to be solved ... or the knowledge of one of ordinary skill in the art ...”
- “The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art.”
- “References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures.”
- “... the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.”

Appellant agrees with these principles as properly understood and applied. For example, Appellant has *not* argued and is *not* arguing that the obviousness rejection is improper due to the inability to bodily incorporate the features of Cho or Young into Verrier. Likewise, Appellant has *not* argued and is *not* arguing that the obviousness rejection is improper due to the lack of an express, written motivation to combine Cho or Young with Verrier.

Rather, Appellant's position is more in line with the principle that the test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. If such person were provided with the three asserted references at the time the present invention was made, that person would have noted that:

- Verrier describes a home-based, wearable, self-contained system for determining the sleep state of a patient, where the system monitors heart rate variability, eyelid movements, and head movements. Monitoring eyelid movement allows Verrier to detect REM (rapid eye movement) sleep state. Verrier also states that they have discovered a relationship between heart function and sleep state, and have taken advantage of that discovered relationship in determining sleep state (see col. 3, lines 60-65).
- Cho describes a method for detecting disordered breathing events that is said to be implementable in an implantable device, the implantable device also delivering therapy to alleviate the disordered breathing once it is detected. Cho states that the device may include an activity sensor, such as a piezoelectric element sensitive to body movements, and that the activity sensor may be used in detecting a sleep state. Cho also mentions a real-time clock, monitoring changes in the QT interval, and monitoring respiratory effort in connection with detection of sleep and/or arousal from sleep.
- Young describes the use of certain chemical substances ("agonists") in the treatment of human disorders of sleep hypoxia and oxygen deprivation. One short passage in the lengthy document mentions that in the course of normal REM-sleep, and to a lesser degree in deep NREM-sleep, atonia of the postural muscles

develops and extends to the muscles of the upper airway, leading to a collapse of the soft tissues, resulting in upper airway obstruction of varying degree.

Considering these references as a whole -- and without being exposed to the teachings of the present application -- the skilled person would have had no reason to combine them in the manner proposed by the Examiner, even if one ignores the glaring differences in the intended applications of the different inventions. The comment in Young regarding atonia of postural muscles in the course of normal REM-sleep, which appears in a section entitled “Pathophysiologic Context of the Invention – Sleep Apneas” (see paragraph 0044), would have been regarded as mere background information on sleep apneas. Such general disclosure regarding an effect of a given medical condition on the body is fundamentally different from an idea to turn the relationship around so as to detect the condition by sensing its effect. Nor would such an idea have had any applicability to the other references, since Verrier already determines sleep state with its disclosed sensors, and Cho expresses no interest in determining the type of sleep state. Furthermore, none of the references mention the possibility of measuring pectoral muscle tone, much less doing so with an implantable device.

The Examiner’s position, on the other hand, does not consider the references as a whole, but amounts to selectively isolating disparate teachings from them and combining those teachings only with the benefit of the inventive insights provided by the present application.

The claim rejections are thus premised on erroneous grounds and on an erroneous characterization of the at least Young, and cannot be sustained. This Appellant’s Statement, viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections of record are without merit.

Respectfully submitted,

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